FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed July 01, 2009. Claim 43 has been amended and new claims 69-71 are added. Applicant's amendments requiring contacting the material with the external surface of the ball and collecting the sample in the collection reservoir from the material introduced to the device necessitated the new grounds of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**.

Status of the Claims

2. Claims 43-71 are pending in this application. Amendments to claim 43 have been reviewed and entered.

3. Claim 56-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) and election made **without** traverse in the reply filed on July 25, 2008 and made final in the office action dated February 2, 2009.

4. Applicants arguments filed on July 01, 2009 have been fully considered and addressed following claim rejections.

5. Claims 43-55 and 69-71 are under prosecution.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 43-52, 54 and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann et al (USPN 5,919,420 issued Jul. 6, 1999) in view of Sharpe (USPN 5,554,537 issued Sep. 10, 1996).

Regarding claim 43, Niermann et al teaches a method of collecting a sample from a material comprising following steps.

Regarding step 'a' (i), Niermann et al provides a device 10 comprising a chamber shaped at one end to form a socket 40 (Fig. 1, and column 4, lines 14-25) and at the other end to form a sample collection reservoir 130 (Fig. 1, and column 3, lines 47-67 and column 4, lines 1-13, step 'a' (i) of the claim).

Regarding step 'a' (ii), Niermann et al teaches a ball 20 housed within the socket 40, wherein at least part of an external surface 27 of the ball 20 in the socket 40 is configured to contact the sample (Figs. 2-4, column 2, lines 5-24, column 4, lines 26-67 and column 5, lines 1-5, column 6, lines 61-67).

Regarding step 'b', Niermann et al teaches that the device 10 is used for "collecting, transferring, analyzing and sorting biological sample" (column 3, lines 49-52) and further teaches the external surface 27 is the environment contacting surface and exposed to the external environment (column 6, lines 61- 65) but do not teach explicitly introducing the material to the device by contacting the material with the external surface of the ball.

Regarding step 'c', Niermann et al teaches rotating the ball (column 2, lines 5-11).

Regarding step 'd', Niermann et al that the device 10 is used for "collecting, transferring, analyzing and sorting biological sample" (column 3, lines 49-52), thus implicitly teaching device is used for sample collection. Niermann et al explicitly do not teach collecting the sample from the material introduced in the device.

Regarding claims 44-47, Niermann et al do not teach absorbent material.

Regarding claim 48, Niermann et al teaches that the sample passes from the collection reservoir 130 (Fig. 2) through an outlet 115 (Fig. 2 and column 4, lines 4-13). Niermann et al also teaches passing of sample from collection reservoir to clinical analyzer via automated sample probe (column 4, lines 7-9), which is reasonably interpreted as an outlet as described in the instant specification (USPGPUB, paragraph 0063).

Regarding claim 49, Niermann et al teaches that collection tube 100, i.e., conduit (Fig. 2) connected to the outlet 115 (Fig. 2, column 3, lines 64-67, and column 4, lines 1-4). Since the instant specification does not provide the limiting definition for conduit, claim is broadly interpreted to include the conduit as tube as defined in the Random house unabridged dictionary.

Regarding claims 50 and 51, Niermann et al teaches measuring the volume of the sample collected in the collection reservoir 130, i.e., small volume (Fig. 2, column 4, lines 3-6), which is reasonably interpreted as performing the analysis of the sample in collection reservoir.

Regarding claim 52, Niermann et al teaches that the sample in the device is connected to a clinical analyzer device via automated sample probe for analysis of the sample (column 4, lines 4-13).

Regarding claim 54, Niermann teaches that the samples are blood, biological or non-biological sample (column 3, lines 51-53 and column 8, lines 43-45).

Regarding claim 69, Niermann et al teaches the external surface 27 of the ball 20 comprises a spherical, substantially continuous surface (Fig. 3, column 8, lines 57-61).

Regarding claim 70, Niermann et al teaches that the ball is rotated and external surface 27 of the ball 20 is exposed to the external environment (column 6, lines 45-65), which is reasonably interpreted as maintaining exterior surface of the ball in contact with the material while rotating the ball.

Regarding claim 71, Niermann et al teaches that the ball 20 housed in socket 40 is rotatable around axle 30 (column 6, lines 6-10), which encompasses ball is rotatable in any direction.

As described above, regarding claims 44-47, Niermann et al teaches that the device 10 is used for sample collection (column 3, lines 50-53). Niermann et al do not teach an absorbent material housed within collection reservoir and in contact with the external surface. However, absorbent material housed within a collection reservoir and in contact with the external surface were known in the art at the time of the claimed invention was made as taught by Sharpe.

Sharpe teaches a method for collecting the sample comprising a device further comprising a scrubber retainer 2 within chamber 3 (Fig. 1). Sharpe further teaches the

scrubber retainer 2 further comprises an absorbent material 7 housed within collection reservoir 3 (Fig. 1, column 3 lines 10-15) and also teaches that the absorbent material is in contact with the external surface of the material (column 2, lines 48-62).

Regarding claim 45, Sharpe teaches that the absorbent material is absorbent filter (column 3, lines 15-20).

Regarding claim 46, Sharpe teaches applying fluid to the material prior to collecting the sample (column 2, lines 35-43).

Regarding claim 47, Sharpe teaches the suspending the sample in a fluid in the collection reservoir (column 2, lines 43-47).

Sharpe further teaches that the absorbent material retains large volumes of liquid and releases liquid when compressed and expand to reabsorb liquid when the compressive force is released to collect large amount of sample in the reservoir in suspension form for further analysis (column 2, lines 35-47 and column 5, lines 4-17).

As described above, Niermann et al implicitly teaches device comprising ball in a socket for collecting samples from the external environment. Sharpe teaches a method for collecting sample by introducing the material to the device by contacting the material with the external surface of the absorbent material for collecting large amount of sample for further analysis. Therefore one having the skill in the art would be motivated to use absorbent material of Sharpe in the ball and socket device of Niermann et al to obtain large sample for further analysis. Since both Niermann et al and Sharpe teaches collecting samples method steps are combinable.

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the step of collecting sample of Niermann et al with absorbent material housed within the collection reservoir of Sharpe with reasonable expectation of success.

An artisan would be motivated to modify the step of collecting sample of Niermann et al with the expected benefit of having an absorbent material retaining large volumes of liquid and releasing a liquid when compressed and expanding to reabsorb liquid when the compressive force is released to collect large amount of sample in the reservoir in suspension form for further analysis as taught by Sharpe (column 2, lines 35-47 and column 5, lines 4-17).

8. Claims 43, 50, 52-53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann et al (USPN 5,919,420 issued Jul. 6, 1999) in view of Sharpe (USPN 5,554,537 issued Sep. 10, 1996) as applied to claim 43 as above and further in view of Shuber (USPN 5,633,134 issued May 27, 1997).

Claim 53 is dependent from claim 52. Claims 52 and 55 are dependent from claim 50, which is dependent from claim 43. Teachings of Niermann et al and Sharpe regarding claims 43, 50 and 52 are described in this office action in section 7.

Regarding claim 53, Niermann et al teaches that the analysis device is a clinical analyzer (column 4, line 9). Niermann et al do not teach a thermocycler device.

Regarding claim 55, Niermann et al teaches that the sample comprises blood and other contaminant sample (column 8, lines 43-45) and further teaches clinical

analyzer to evaluate sample (column 4, lines 4-13). Niermann et al do not teach evaluating substance for a DNA. However, sample analysis using thermocycler device for DNA was known in the art at the time of the claimed invention was made as taught by Shuber.

Shuber teaches a method for collecting sample comprising blood and biological fluid samples for further DNA analysis (column 2, lines 44-60). Shuber also teaches analysis comprises evaluating the substance DNA (Example 1 and column 2, lines 28-37) using a thermocycler (column 4, lines 63).

Combined teachings of Niermann et al, Sharpe and Shuber provide a method for collecting sample using a ball and socket device and evaluating the DNA of the sample. Shuber et al also teaches use of thermocycler provides a rapid cost effective process for simultaneously testing large number of individuals for the presence or absence of multiple mutations in one gene or multiple genes (Abstract and Example 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the analysis step of the collected sample of Niermann et al with DNA analysis step of Shuber with reasonable expectation of success.

An artisan would be motivated to modify the analysis step of the collected sample of Niermann et al with the expected benefit of using a thermocycler and providing a rapid cost effective process for simultaneously testing large number of individuals for the presence or absence of multiple mutations in one gene or multiple genes as taught by Shuber (Abstract and Example 2).

Response to remarks from the Applicants

Claim Rejections under 35 U.S.C. § 102(b)

9. Applicant's arguments filed on July 1, 2009 with respect to claims 43, 48-52 and 54 as being anticipated by Niermann et al have been fully considered (Remarks, pgs. 7-9) but are moot in view of claim amendments, withdrawn rejections and new grounds of rejection as set forth in this action necessitated by claim amendments. Applicant's arguments with respect to teachings of Niermann et al as it pertains to the rejections made in this office action are addressed in section 10.

Claim Rejections under 35 U.S.C. § 103(a)

10. Applicant's arguments with respect to claims 43-47 and 43, 50, 52-53 and 55 as being unpatentable over combination of references have been fully considered (Remarks, pgs 9 and 10) but are not persuasive as discussed below.

Applicant argues that Niermann et al do not teach collecting sample in a collection reservoir by rotating a ball over the material (Remarks, pg. 7, last paragraph). This argument is not persuasive because as described above in section 7, Niermann et al implicitly teaches a ball in a socket device for sample collection and Sharpe explicitly teaches a method for collecting sample by introducing the material to the device by contacting the material with the external surface of the absorbent material for collecting large amount of sample for further analysis (column 2, lines 48-62).

Applicant's remaining arguments are directed to Niermann et al not teaching collecting sample with the ball in a socket device (Remarks, pg. 9, paragraph 3). This argument is not persuasive for the same reasons as described above.

Applicant further argues that neither Sharpe nor Shuber cure the deficiency of the primary reference (Remarks, pg. 9, paragraph 5). These arguments are not persuasive because as described above in sections 7 and 8, method steps not taught by Niermann et al are taught by Sharpe or Shuber. Also Applicant has not traversed the teaching, suggestions and motivations provided by either Sharpe or Shuber to apply the sample collection method using the device of Niermann et al and therefore arguments are not persuasive. Furthermore, Applicant has not provided any support evidence as to why sample collection method steps of Sharpe would not work with the device of Niermann et al. Since Niermann et al, Sharpe and Shuber teach all recited steps of the method as claimed arguments are not persuasive.

Conclusion

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Douglas) Schultz can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat

Examiner, Art Unit 1634

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634